IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

----------X

ANNIE TUMMINO, *et al.*,

Plaintiffs,

No. 12-CV-0763 (ERK/VVP)

v.

MARGARET HAMBURG, *et al.*,

Defendants.

----------X

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR A STAY OF MEMORANDUM AND ORDER FILED ON APRIL 5, 2013

INTRODUCTION

A stay of this Court's Memorandum and Order ("Order") filed on April 5, 2013, should not be granted. The harm to Plaintiffs, and the women whose interests they represent, will be certain, significant and irreparable. Women of all ages have waited over 12 years for the removal of arbitrary, capricious and politically motivated restrictions that stand in the way of exercising their fundamental right to access emergency contraception and avoiding unwanted or unintended pregnancy. Any further delay is not merely prejudicial to Plaintiffs and the women they represent: everyday that a stay is in place, it is life-altering.

Defendants have failed to satisfy their burden to meet the legal requirements for a stay. As this Court's Order makes clear, Defendants have little likelihood of success on the merits of their appeal. They have not shown that compliance with this Court's Order will cause irreparable injury.

A stay for the duration of the Defendants' appeal will perpetuate – for months, or years – the unconscionable delays that have permeated the Defendants' actions with regard to emergency contraception. Defendants' arguments that the approval of an amended Supplemental New Drug Application ("SNDA") for Plan B One-Step eliminates the possibility of irreparable harm ring hollow in light of the record in this case showing the burdens of age, identification and point-of-sale requirements – all of which are to some extent left in place by their eleventh-hour decision concerning Plan B One-Step. *See, e.g., Tummino v. Hamburg* (hereinafter "*Tummino II*"), No. 12-CV-763 (ERK)(VVP), 2013 U.S. Dist. Lexis 49666 **36-37 (E.D.N.Y. April 5, 2013) ("[M]ost younger adolescents, including 'many poor or disadvantaged women,' 'will be denied access because they do not have a driver's license, passport, or other form of identification with which to verify their age.'"); *see also Tummino v. Torti*, (hereinafter "*Tummino I*"), 603 F.Supp.2d 519, 540 (S.D.N.Y. 2009) (noting burden imposed by prescription requirement and fear and anxiety it causes).

Instead, Defendants' political decision-making concerning emergency contraception – which has tainted this litigation for over eight years – is once again apparent. Rather than comply with this Court's Order, Defendants approved an amended SNDA which permits Teva Women's Health, Inc. to market Plan B One-Step in locations with an on-site pharmacy only to those who are 15-years of age and older and requires identification to verify age.[1] For those under the age of 15, Plan B One-Step is no longer available by prescription. *See* Defendants' Memorandum in Support of Motion for a Stay Pending Appeal (hereinafter "Stay Motion"), ECF

[1] The requirement to show identification, in itself, is sufficient to intrude on these constitutionally protected interests, but now women and teens must stand in a store line and disclose their name, age and possibly their address to random employees before purchasing a product to which they have a fundamental right of privacy, rather than to a pharmacist who has been trained to uphold confidentiality. An informational privacy claim was raised by Plaintiffs in their Fifth Amended Complaint. *See* ECF No. 207 at ¶ 172. Defendants' claim that "requirement to show proof of age to purchase a product has been held not to impair a legally protected interest." Stay Motion at 11 n.8.

No. 91-1 at 3. All other levonorgesterel products remain restricted behind the pharmacy counter and only available to those age 17 and older without a prescription who can show government issued identification, or by prescription to those under 17 or those who cannot produce government-issued identification. Defendants' reliance on the approval of the amended SNDA – conduct undertaken with full knowledge that it would not satisfy either the letter or spirit of this Court's order – should not weigh in their favor in support of a stay.

Even with the approval of the Plan B One-Step amended SNDA, countless women will experience daily substantial and irreparable harm through unwanted pregnancy, or the risk of pregnancy, as significant barriers which block timely access remain in place pending Defendants' appeal. *See Tummino II*, 2013 U.S. Dist. LEXIS 49666, *5 (emergency contraception is most effective when taken immediately after intercourse and preferably no later than 24 hours later). As this Court found, Defendants' persistent refusal to provide over-the-counter access to emergency contraception – even in the face of overwhelming scientific evidence – has relied on a pretextual "excuse to deprive the overwhelming majority of women of their right to obtain contraceptives without unjustified and burdensome restrictions." *Tummino II*, 2013 U.S. Dist. LEXIS 49666 at *15. Defendants' bad faith actions, inaction and "intolerable" delay throughout this litigation, and during the "administrative agency filibuster" in which it took over 12 years to debate, and politically deflect, the over-the-counter switch of emergency contraception, cannot be ignored or rewarded. *Id.* at **105-06. Where the "competence and good faith of public agencies . . . that provide critical services to the public" are called into question, the public interest weighs against a stay. *See V.S. v. Muhammad*, Nos. 07-CV-0213 (DLI)(JO), 07-CV-1281 (DLI)(JO), 2008 U.S. Dist. LEXIS 96099, *10 (E.D.N.Y. Nov. 24, 2008). The benefits to the public interest are apparent: the right of women and girls to

timely access to safe and effective contraception and the accountability and integrity of the scientific review process entrusted by the public to our nation's Food and Drug Administration. The public interest overwhelmingly weighs in favor of execution of the Court's Order.

ARGUMENT

I. Standard of Review

Federal Rule 62(c) gives the Court discretion to stay an injunction pending appeal "on terms that secure the opposing party's rights." The Second Circuit has identified four factors to be considered in issuing a stay pending appeal under Fed. R. Civ. P. 62:

> (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

In re World Trade Center Disaster Site Litigation, 503 F.3d 167, 170 (2d Cir. 2007). However, the "degree to which a factor must be present varies with the strength of the other factors, meaning that 'more of one [factor] excuses less of the other.'" *Id*. (internal quotation marks omitted); *Thapa v. Gonzales*, 460 F.3d 323, 334 (2d Cir. 2006) ("We have treated this criteria somewhat like a sliding scale, citing approvingly other circuits' formulation that the necessary level or degree of possibility of success will vary according to the court's assessment of the other stay factors . . . .") (internal quotation marks and alterations omitted)).

As explained below, here, no factor strongly favors the Defendants. They must, therefore demonstrate that they satisfy their burden as to each, including a strong showing that they are likely to succeed on the merits of their appeal. Defendants cannot meet this burden. A stay should be denied.

II. Defendants Do Not Meet The Requirements for a Stay

A. Defendants Have Not Made a Strong Showing That They are Likely

to Succeed on the Merits of Their Appeal

This Court found, based on an extensive factual record, that Defendants arbitrarily, capriciously and unreasonably denied the Citizen Petition based on actions and decisions that were "politically motivated, scientifically unjustified, and contrary to agency precedent." *Tummino II*, 2013 U.S. Dist. LEXIS 49666 at *86. The Order includes extensive cites to the record which support this conclusion. On appeal, Defendants are unlikely to overcome these facts and the legal conclusions that necessarily follow from them. It is telling that the Defendants do not argue that their actions were reasonable. Nor do they argue that this Court's findings regarding the safety and efficacy of unrestricted over-the-counter access to levonorgesterel-based emergency contraception is clearly erroneous. Rather, they argue only that this Court's remedy was incorrect. As a result, they have not established their entitlement to a stay on the grounds that they are likely to succeed on the merits of their appeal.

1. Defendants Have Not Established a Strong Likelihood of Success on Their Claim That This Court Exceeded its Authority by Including One-Pill Products Within Its Ordered Relief

Defendants argue that this Court had no jurisdiction over the Plan B One-Step SNDA and, therefore, exceeded its authority in granting relief as to that product. They further argue that the Court erred in considering evidence related to the Plan B One-Step SNDA, or the facts surrounding the denial of that SNDA. *See* Stay Motion at 2, 5-8. These claims, however, do not establish that Defendants are likely to succeed on appeal.

In the first instance, Defendants' attempt to frame this issue as one of subject matter jurisdiction is misplaced. This Court did not, and in fact explicitly made clear that it was not, exercising jurisdiction over the Plan B One-Step SNDA:

> The Plan B One-Step sponsor has not taken an appeal to the Court of Appeals for the District of Columbia, which would have jurisdiction to review it. *See* 21 U.S.C. § 355(h). The only decision subject to review here is the denial of the Citizen Petition; I do not have any authority to review the denial of the Plan B One-Step SNDA for the purpose of granting relief. Nevertheless, as observed earlier, the two were clearly linked together . . . .

Tummino II, 2013 U.S. Dist. LEXIS 49666 at **63-64. *See also id.* at **18-19 ("The directive of the Secretary did not directly apply to the Citizen Petition, the denial of which I have subject matter jurisdiction to review. Nevertheless, the denial of the Citizen Petition was inevitable after the Secretary ordered the FDA to reject the SNDA for Plan B One-Step.").

The denial of the Plan B One-Step SNDA and the grounds therefore were nonetheless highly relevant to the Court's consideration of the Citizen Petition, because Defendants made them so. *Id.* at *88 (quoting the Citizen Petition Denial Letter, stating that data needed for the approval of the Plan B One-Step SNDA "is *directly relevant* to whether those data were needed for the same approval of Plan B *because of the similarities between the products*") (emphasis in Order). As this Court found:

> [O]nce the Secretary directed the FDA to deny the Plan B One-Step SNDA, the FDA had no possible basis on which to approve the Citizen Petition. The same lack of data that the Secretary said caused her to deny the Plan B One-Step SNDA also doomed the Citizen Petition because it lacked the same data, which were, as the FDA acknowledged, impossible to provide. . . [I]t is not possible to exercise meaningful judicial review over the denial of the Citizen Petition without considering the propriety of the Secretary's actions regarding the Plan B One-Step SNDA. Indeed, the FDA's own justification for its Citizen Petition action indicates a substantial reliance on the Plan B One-Step SNDA process. The FDA spent a considerable portion of the Citizen Petition Denial Letter discussing the Plan B One-Step SNDA and the various studies submitted in its support. More significantly, the very reason the FDA claimed it denied the Citizen Petition was the lack of age-specific data, *as compared to* that submitted with the Plan B One-Step SNDA.

Id. at **63-64 (emphasis in Order). *See also id.* at **18-19 ("[T]he denial of the Citizen Petition was inevitable after the Secretary ordered the FDA to reject the SNDA for Plan B One-Step

because the Secretary concluded that the sponsor's 'label comprehension and actual use studies . . . do not include date on all ages for which the drug would be approved and available over-the-counter.'"); *id.* at *72 (the FDA's decision to deny the Citizen Petition was "compelled by the reason underlying the Secretary's order to reject the Plan B One-Step SNDA").

In addition to finding that this evidence was relevant in addressing the actions of Defendants in denying the Citizen Petition, the Court also found ample evidence in the record, unrelated to the Plan B One-Step SNDA, to support granting the Citizen Petition and as to why Defendants' actions in denying it were arbitrary, capricious and subject to reversal. *See, e.g., id.* at *85 (actual use study with original Plan B SNDA established "excellent compliance" with label instructions); *id.* at **39-44 (summarizing evidence on extrapolation considered by the Court in its 2009 opinion); *id.* at *75 ("[T]he suggestion that the plaintiffs need to provide 'additional data' comparable to that in the Plan B One-Step application 'to support a switch of Plan B for women younger than 17 years of age' is simply a complete pretext . . ."); *id.* at *76 ("Citizen Petition Denial Letter also failed to acknowledge the FDA's own policy and precedent of approving drugs for over-the-counter sale even where there is real concern about their safety."); *id.* at *76 ("[T]he Citizen Petition Denial Letter is unsound . . . [because] it failed to offer any explanation as to why Plan B should be treated differently from other drugs so as to require numerous deviations from agency policies and practices."); *id.* at *77 ("While these unexplained departures from precedent alone render the denial [of the Citizen Petition] arbitrary, capricious, and unreasonable, they are not the only reasons for reversing the denial of the Citizen Petition.").

As this Court has found in consideration of the record in *Tummino v. Torti* (hereinafter "*Tummino I*"),[2] 603 F. Supp. 2d 519 (E.D.N.Y. 2009) and *Tummino II*, Defendants' own conduct has inextricably tied the one- and two-pill products. *See Tummino I*, 603 F.Supp.2d at 543; *Tummino II*, 2013 U.S. Dist. LEXIS 49666 at **18, 63-65. Numerous findings of this Court demonstrate the similarities between the two. The one-pill and two-pill products "contain the same total dose of levenorgestrel." *Tummino II*, 2013 U.S. Dist. LEXIS 49666 at *4. The label comprehension study, found by the Court to support unrestricted over-the-counter access, applies "equally well to both one-pill and two-pill products." *Id.* at **79. And, as this court explained:

> [T]he FDA itself acknowledged the 'overlapping elements of labeling between Plan B One-Step and the other levonorgestrel [emergency contraception] products. Examples of these elements include the indication for the product, the appropriate time to take the product (as soon as possible but within 72 hours), and the warnings that the product should not be used as regular birth control and will not protect from sexually transmitted diseases. In addition, safety data generated by these trials for levonorgestrel used as emergency contraception may be applicable to both products. Therefore, some data generated by these studies may be applicable to the other levonorgestrel [emergency contraceptives].'

Id. at *81 (citing Letter from Andrea Leonard-Segal, M.D., Center for Drug Evaluation and Research, FDA, to Duramed Pharmaceuticals at 2 (Dec. 17, 2010), ECF No. 23-3) (alterations in original).

The Citizen Petition seeks unrestricted over-the-counter status for Plan B and drugs that are "equivalent" to Plan B.[3] Here, the Court found that one-pill products are included within the relief that flows from the granting of the Citizen Petition. This conclusion is unremarkable given the extensive record before the Court, and the changing

[2] By Order dated March 6, 2013, ECF No. 78, the Court amended its opinion of March 23, 2009. Unless otherwise specified, citations to *Tummino I* refer to sections of the opinion that were not altered by the Court's March 6, 2013 Order.

[3] The Citizen Petition requests that "the FDA exempt from prescription-dispensing requirement, pursuant to 21 U.S.C. § 353(b)(3) and 21 C.F.R.. § 310.200(b), *Preven*™, Plan B®, and any new drug eligible for filing an abbreviated new drug application because of its equivalence to *Preven*™ or Plan B®.

circumstances that have resulted from the protracted bad faith delay for over 10 years that has occurred since the FDA first determined that levonorgestrel-based emergency contraception products were appropriate for unrestricted over-the-counter access. *See id.* *40 (citing 2003 FDA Advisory Committee recommendation to approve Plan B SNDA for over-the-counter status without age or point-of-sale restrictions); *see also Tummino I*, 603 F.Supp.2d at 531-34; 545-46.

In addition, the relief afforded by the Court appropriately addresses the harms that Plaintiffs seek to remedy and Defendants' protracted egregious conduct. As this Court explained, Plaintiffs "ask that the Citizen Petition be granted and that the FDA be required to make all levonorgestrel-based emergency contraception, including Plan B, available for over-the-counter sales." *Id.* at *19. *See also id.* at *7 (Plaintiffs "seek to expand the availability of Plan B and all emergency contraceptives."). Plaintiffs sought this relief to end the harms caused by the FDA's ongoing refusal, significant departures from policy and for improper political reasons, to make safe and effective levonorgestrel-based emergency contraception available over-the-counter without age or point-of-sale restrictions.

In a typical case, the proper course in light of agency misconduct is remand. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) (holding that the proper course, "except in rare circumstances, is remand to the agency"). As this Court found, however, this is not a "run-of-the mill case;" "bad faith has permeated consideration of the Citizen Petition":

> More than twelve years have passed since the Citizen Petition was filed and eight years since this lawsuit commenced. The FDA has engaged in intolerable delays in processing the petition. Indeed, it could accurately be described as an administrative agency filibuster. . . . The plaintiffs should not be forced to endure,

> nor should the agency's misconduct be rewarded by, an exercise that permits the FDA to engage in further delay and obstruction.

Tummino II, 2013 U.S. Dist. LEXS 49666 at **105-06. In cases such as here where agency conduct is so egregious, in bad faith and where remand is highly inappropriate, *id* at **102-03 (declining to remand), the Court must necessarily have the authority to fashion a complete and appropriate remedy. *See Am. Biosci. Inc. v. Thompson*, 269 F.3d 1077, 1086 (D.C. Cir. 2002) (declining to remand for the second time following FDA's arbitrary and capricious conduct). The relief ordered by the Court reflects the unique and extraordinary facts presented by Defendants' conduct.[4]

In pressing this argument, Defendants are in effect using their own misconduct in delaying action on the Citizen Petition to deny women the benefit of advances in medicine that have occurred over the last decade. Over the course of this protracted litigation, and due directly to Defendants' bad faith conduct and undue delays, while the precise relief that Plaintiffs seek has had to change, *see id.*at *104 (noting that not all of the relief initially sought in the Citizen Petition was still necessary), the fundamental nature of that relief has not. Defendants have not established their likelihood of success on appeal on this issue.

2. Defendants Have Not Established a Strong Likelihood of Success on Their Claim That the Court Erred in Not Remanding to the FDA for Further Action

The Court did not exceed its authority in ordering the FDA to make "levonorgesterel-based emergency contraceptives" available OTC rather than remanding to the FDA for further agency action. As the FDA itself acknowledges, where the agency record already has been fully

[4] Defendants claim that this Court's Order was more in the nature of mandamus, and therefore it was improper for the Court to direct Defendants to undertake a specific course of action. Defendants are confusing relief issued pursuant to 5 U.S.C. § 706(1) with relief issued pursuant to 5 U.S.C. § 706(2). *See generally Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 63 (2004) (comparing § 706(1) with mandamus in that the only agency action that can be compelled under § 706(1) must be action legally required). Here, Plaintiffs have not sought a mandamus, nor did the Court order one. *Tummino II*, *64 (applying standard of review under § 706(2)).

developed and remand would serve no useful purpose, remand is not required. *See* Stay Motion at 10. Those are precisely the circumstances here: the Court *already* remanded this case to the FDA in 2009, and the FDA has proved through its inaction and bad faith over the past four years that another remand would lead merely to Plaintiffs' Citizen Petition languishing for several years more. As the Court explained in *Tummino I*, remand would serve no useful purpose and the court should order the desired agency action when: (1) "a court has found that an agency decision is not supported by the record, but 'the record has been fully developed'"; or (2) when a justification for agency action "runs counter to the evidence and is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." 603 F. Supp. 2d at 549 (internal quotations marks omitted).

Here, the Court correctly concluded that Plaintiffs had satisfied both parts of this test and were entitled to an order that granted the Citizen Petition. It refused to remand for further agency action for a number of crucial reasons. First and foremost, the Court's previous conclusion in 2009 that a remand was warranted because the government "'could be trusted to conduct a fair assessment of the scientific evidence'" *id*., has, unfortunately, proven to be incorrect. After the Court remanded to the FDA for further consideration in 2009, the agency took no action whatsoever on the Citizen Petition for almost three years and finally denied it only *after* Plaintiffs had filed a motion for contempt. *Tummino II*, 2013 U.S. Dist. LEXIS 49666, *10.

Further, at the end of 2011, the FDA actually agreed, based on the scientific evidence, to approve Teva's SNDA to make Plan B One-Step over-the counter for all ages and with no point of sale restrictions. But Secretary Sebelius took the unprecedented step of overruling the FDA's scientifically sound decision, therefore requiring the FDA to also deny the Citizen Petition. *Id.*

at **11-13. As this Court's careful review of the record demonstrates, as with the significant departures from agency norms that occurred with Plan B, decision-making regarding Plan B One-Step was wrested from the usual decision-makers to upper management, who then provided implausible reasoning, contrary to the evidence, for denying the Plan B One-Step SNDA. *Id.* at *21 ("Perhaps the most significant departure from agency practice was the intervention of the Secretary of Health and Human Services.").

The record before the agency is also fully developed and there is no need for further review by the FDA of whether a switch to complete OTC status is scientifically sound. The FDA itself concluded that it was for Plan B One-Step when it agreed to approve Teva's original SNDA in 2011. And, even prior to that decision, as early as 2003 when FDA's own Advisory Committee voted to approve emergency contraception over-the-counter without restrictions and through decisions by its scientific review staff which were not followed due to improper political influence of the Bush White House and interference by high level FDA officials. *See Tummino I*, 603 F. Supp. 2d at 528; *Tummino II*, 2013 U.S. Dist. LEXIS 49666 at **8-12, 74-84. The FDA has exercised its agency expertise, which was thwarted by improper political influence, arbitrary agency action and the Secretary's unprecedented actions in overruling FDA. In such circumstances, after over 10 years, it would be futile to order another remand.

In addition, the Court accurately concluded that "no statute or regulation requires the FDA to engage in administrative rulemaking upon approval of a citizen petition or *sua sponte* reconsideration of a drug's prescription-only status" and went further in its legal conclusions rejecting FDA's argument that this matter should be remanded for administrative rulemaking:

> [E]ven if the defendants' arguments would be sufficient to carry the day in the run-of-the-mill case, the bad faith that has permeated consideration of the Citizen Petition, not to speak of the Plan B sponsor's applications, should rule out such relief here. More than twelve years have passed since the Citizen Petition was

> filed and eight years since this lawsuit commenced. The FDA has engaged in intolerable delays in processing the petition. Indeed, it could accurately be described as an administrative agency filibuster. Moreover, one of the devices the FDA has employed to stall proceedings was to seek public comment on whether or not it needed to engage in rulemaking in order to adopt an age-restricted marketing regime. After eating up eleven months, 47,000 public comments, and hundreds of thousands, if not millions, of dollars, it decided that it did not need rulemaking after all. The plaintiffs should not be forced to endure, nor should the agency's misconduct be rewarded by, an exercise that permits the FDA to engage in further delay and obstruction.

Tummino II, 2013 U.S. Dist. LEXIS 49666 at **103, 106. The Court acted entirely within its authority in ordering the FDA to grant the Citizen Petition, and Defendants have not established a likelihood of success on this issue on appeal.

Finally Defendants incorrectly assert that they need not establish a likelihood of success on the merits as to either of their claims, but only a "substantial possibility." *See* Stay Motion at 4. Defendants would only be entitled to a reduction of their burden on this point if one or more of the other factors weighed strongly in their favor. *See Thapa*, 460 F.3d at 334 (holding that "the necessary level or degree of possibility of success will vary according to the court's assessment of the other stay factors") (internal quotation marks omitted). Here, as shown below, Defendants have failed establish any of the remaining factors, much less made a strong enough showing to reduce their burden under the likelihood of success prong. In any event, Defendants have not established that they have even a "substantial possibility" of succeeding on the merits of their appeal.[5]

B. Plaintiffs and the Women They Represent Will be Irreparably Injured by a Stay

[5] Defendants assert on the one hand that they need only establish a substantial possibility of success on the merits, but on the other argue that because they have established "a very substantial likelihood of success," their burden to establish that a stay serves the public interest is reduced. Stay Motion at 12. While Defendants are not entitled to have it both ways, ultimately, it does not matter because they have failed to meet their burden under either standard as to either prong.

In arguing that Plaintiffs and the women they represent will not be irreparably injured by a stay, Defendants suggest that by approving the Plan B One-Step amended SNDA, they have somehow simplified the regulatory regime for emergency contraception, thereby making levonorgestrel-based drugs more readily accessible to women of all ages. *See* Stay Motion at 3 & n.1. Defendants are mistaken. In eliminating the dual-marketing regime for Plan B One Step, Defendants have replaced it with a convoluted triple-tiered marketing scheme that will only increase the confusion that already prevents women from obtaining timely access to levonogestrel-based products. Specifically, women and retailers across the country will be forced to operate under the following set of nonsensical rules: (1) women 15 years-of-age or older with adequate proof of age will be permitted to purchase Plan B One-Step, which will only be available on the shelves in stores with on-site pharmacies; (2) other levonorgestrel-based products will remain behind the counter, but will be available without a prescription to women over 17 years-of-age who have government issued proof of age; and, (3) women who lack adequate proof of age or are under the age of 15 will not have access to Plan B One-Step and must obtain a prescription. *See* Decl. of Janet Woodcock, M.D., ECF No. 91-2 at ¶ 3b ("The newly approved Plan B One-Step no longer includes a prescription version for younger age groups"). After arguing to this Court that the FDA reasonably believed that younger women lack the capacity to follow instructions for the proper use of the two-pill product, *see, e.g.*, FDA Response to Order to Show Cause, ECF No. 23 at 28-33, 35; Defs.' Memorandum of Law in Opposition to Plaintiffs' Post-Remand Motion for Preliminary Injunction and Summary Judgment, ECF. No. 37 at 43. Defendants are now advocating for a regime under which the youngest women who need emergency contraception will *only* be able to use a two-pill product.

Even after the FDA's eleventh-hour approval of the Plan B One-Step amended SNDA, women under the age of 15 will continue to face the obvious barrier of having to find a physician and obtain a prescription in order to access emergency contraception. Moreover, the unjustifiable point-of-sale restrictions left in place by the amended SNDA will continue to present barriers to *all* women: many women do not live near a store with an on-premise pharmacy; many women – especially adolescents and immigrants – do not have government-issued identification or other proof of age, and still more do not want to reveal their identities to the seller. *See Tummino II*, 2013 U.S. Dist. LEXIS 49666, **15-17 (summarizing evidence); BRENNAN CENTER FOR JUSTICE, CITIZENS WITHOUT PROOF: A SURVEY OF AMERICANS' POSSESSION OF DOCUMENTARY PROOF OF CITIZENSHIP AND PHOTO IDENTIFICATION 3 (Nov. 2006), *available at* http://www.brennancenter.org/analysis/citizens-without-proof ("As many as 11 percent of United States citizens – more than 21 million individuals – do not have government-issued photo identification."); *id.* (noting that minority citizens and citizens with comparatively low-incomes are less likely to possess photo identification). Left in place, these restrictions will continue to delay or, in some instances, altogether prevent women from accessing emergency contraception, thereby implicating their fundamental rights. *See, e.g.*, *Carey v. Population Servs. Int'l*, 431 U.S. 678, 685 (1977) (explaining, in context of evaluating the constitutionality of restrictions on purchase of contraception, that the right to privacy protects the decision whether to beget a child). Such harm cannot be adequately compensated by a monetary award, and so it is irreparable. *See Wisdom Imp. Sales Co. v. Labatt Brewing Co.*, 339 F.3d 101, 113 (2d Cir. 2003). *See also Elrod v. Burns*, 427 U.S. 347, 373 (1976) (holding that loss of constitutional "freedoms . . . unquestionably constitutes irreparable injury"); *Women's*

Med. Ctr. of Nw. Hous. v. Bell, 248 F.3d 411, 422 (5th Cir. 2001) (affirming district court's finding of irreparable harm based on threat to women's constitutional right to privacy).

Defendants incorrectly claim that a stay will not injure the Plaintiffs because they are all "at least 15 years old" and, therefore, will be able to obtain one form of emergency contraceptive containing levonorgestrel – Plan B One-Step – without a prescription. Stay Motion at 3, 11.[6] This argument is flawed for at least two reasons. First, this argument misconstrues the nature of Plaintiffs' claims. Throughout this litigation, Plaintiffs have sought unrestricted over-the-counter access to levonorgestrel-based contraception not only for themselves, but for all other women. *See* ECF No. 56-2 ¶ 8 and ECF No. 207, Case No. 05-CV-366 ¶¶4-12, 28 (National Women's Liberation "is a feminist group with several priority areas that include the fight for unrestricted access to birth control . . . for all women regardless of age." and each organizer brings this action on her own behalf and on behalf of all women who need emergency contraception).[7] This means removal of *all* scientifically unsupported, arbitrary, capricious and politically motivated age restrictions, identification requirements and point-of-sale requirements which is clearly not what Defendants' approval of the Plan B One-Step amended SNDA has done. Second, it misstates the facts as pled in the Second Amended Supplemental Complaint, which specifies that Plaintiff Tracy Gaffin is suing on behalf of her two daughters, one of whom was only 12 years-old on May 23, 2012. ECF No. 56-2 at ¶ 9.

[6] The best that Defendants can say on this point is that the Plaintiffs will "soon" have access, Stay Motion at 11-12, but they provide no indication if "soon" means within days, weeks, or months.

[7] Defendants' argument that Plaintiffs have no injury because they can now allegedly obtain some form of emergency contraception by battling the barriers erected by their differential treatment of this safe and effective over-the-counter drug is a familiar refrain. Previously, the Court rejected Defendant FDA's argument that the adolescent Plaintiffs suffered no injury when it changed Plan B's status to prescription only for ages 16 and under because their parents could allegedly purchase it for them. *Tummino I*, 603 F. Supp. 2d at 540. More importantly, Plaintiffs' standing to seek the relief sought here is well settled. *Id.* at 540-42. *See also* Transcript of Civil Cause for Conference Before the Honorable Edward R. Korman, dated April 27, 2012, at 138-45, 149.

In short, a stay of the Court's Order would compound the already existing injury created by years of Defendants' denial of access to this safe and effective form of contraception. Defendants' bad faith actions and "intolerable delay" for over 12 years in this case and processing the Citizen's Petition have denied countless women and girls the ability to control their reproduction for political expediency. "[P]laintiffs should not be forced to endure, nor should the agency's misconduct be rewarded by[]" a stay which "permits the FDA to engage in further delay and obstruction." *Tummino II*, 2013 U.S. Dist. LEXIS 49666, *106.

C. Defendants Will Not Suffer Irreparable Injury in the Absence of a Stay

Defendants contend, first, that their showing of irreparable injury as movant is reduced because "the government has demonstrated above a very substantial likelihood of success on appeal." Stay Motion at 12 (citing *Mohammed v. Reno*, 309 F.3d 95, 101 (2d Cir. 2002)). This assertion is incorrect because, as shown *supra* at Point II.A, Defendants have not demonstrated a substantial likelihood of success on appeal. To the extent that this assertion is an acknowledgment that Defendants cannot meet the higher standard for showing they will suffer irreparable harm, Plaintiffs agree, but Defendants' claim of irreparable harm fails even under the inapplicable reduced standard.

Defendants engage in sophistry through their primary argument, that "FDA and the public would be irreparably and immediately harmed if a drug product that purported to be 'FDA approved' were approved instead at the direction of a court." Stay Motion at 12. This Court has found that the FDA itself diverged from the public interest, as well as its own procedures, policies and standards in its persistent refusal to make safe and effective emergency contraception available over-the-counter. *Tummino II*, 2013 U.S. Dist. LEXIS 49666 at *87. It is the FDA which has acted contrary to its legal obligations. Defendants' contention to the

contrary turns reality – as found by this Court after extensive proceedings and upon record evidence – on its head.

Improperly confusing the merits of their appeal with where the public interest lies here, Defendants claim that this Court's finding that the Citizen Petition should be granted is not a method by which the status of an approved drug product can be changed. This however, is a misstatement of the law and has no relationship to Defendants' burden to prove that the public interest weighs in favor of staying implementation of the Court's decision. This argument was rejected years ago by this Court in its decision on dispositive motions in 2009. To the extent that the government continues to argue an already settled legal issue, the Court's adjudication is well founded in record evidence and law. As this Court found:

> [T]here are various means by which the FDA can switch a prescription-only drug to non-prescription status. See 21 U.S.C. § 353(b)(3). Such a switch can be initiated by the Commissioner, 21 C.F.R. § 310.200(b), by any interested person who files a citizen petition, id § 10.25(a), or by the request of a drug sponsor, id § 310.200(b). Within 180 days of receipt of a citizen petition, the Commissioner must either approve or deny the petition or provide a 'tentative response [to the petitioner], indicating why the agency has been unable to reach a decision on the petition. Id § 10.30(e)(2)(iii).

See Tummino I, 603 F. Supp. 2d at 525 as amended by March 6, 2013 Order, ECF No. 78.

Defendants' argument that harm will befall the proper and ordinary operation of the regulatory process if the Court does not stay enforcement of its injunction is wholly misplaced given that it is the FDA itself that has engaged in improper and substantial departures from the regulatory process. The Court's Order actually works to restore the proper outcome here, which is, based on the conclusions of the medical and scientific experts at the FDA, untainted by political interference, that levonorgestrel-based

emergency contraception should be available over-the-counter without age or point-of-sale restrictions.

1. Defendants Claim of "Market Confusion" Does Not Support a Stay

Defendants claim that market confusion will result if no stay is granted and, in the future, due to reversal on appeal, there is a change in the status of the availability of emergency contraception.[8] This, they assert, would injure Defendants and the public interest. This argument does not establish Defendants' entitlement to a stay. Changes in drug status do not create unacceptable market disruption as a matter of law, or as a matter of routine, nor has any record been established by Defendants that such would occur in the event of a reversal.

Changes in approved drug status occur all the time.[9] Routinely, drugs are taken off store shelves; drugs are approved; and old over-the-counter drugs are dropped by companies and some are recalled with little or no notice because of manufacturing problems, dangers to the public or changes in the understood medical implications.[10] Consumers adjust to a changing marketplace every day.

Moreover, Defendants' argument is undermined by their own actions concerning emergency contraception. To the extent that "market confusion" is a real concern, the FDA itself has created its own "market confusion" by approving yet another change in the status and

---

[8] This argument is also dependent on showing a likelihood of success on the merits, which as demonstrated *supra*, has not been established.

[9] *See e.g.*, Food and Drug Administration Monthly Drug Approval Reports which list, *inter alia*, the many approved drugs which have a change in status on a daily basis at the agency: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.MonthlyApprovalsAll.

[10] It is not uncommon for the public to encounter new restrictions on commonly available medication. For example, aspirin, which is readily available, is no longer advised to be given to children. Cough medicine with codeine, once readily available, is no longer on the shelves. Pseudoephedrine has gone from being readily available to now being only available with identification. It bears noting, that emergency contraception – unlike all these other examples – has been found by FDA to pose no danger to the health of the user. *Tummino II*, 2013 U.S. Dist. LEXIS 49666, **11-15.

purchasing of emergency contraceptives with its approval of the amended SNDA for Plan B One-Step with restrictions on requiring identification, limiting point-of-sale, and age limitations, but leaving the majority of emergency contraceptives behind the pharmacy counter, still only available to those under 17 and bya prescription and requiring government issued identification. Defendants' own recent actions have created a regime that is arguably even more confusing than before. *See Tummino II*, 2013 U.S. Dist. LEXIS 49666, **15-16. *See also* Declaration of Tracey A. Wilkinson, M.D., M.P.H., in Support of Plaintiffs' Motion for Preliminary Injunction and Summary Judgment, ECF No. 6 at ¶¶ 4-10 (factually detailing numerous "barriers that are created or exacerbated by the FDA's unusual treatment of emergency contraception").

In response to a question posed by the Court on April 29, 2011, asking what benefit Plaintiffs would gain from granting of the Citizen Petition that they could not gain from approval of the Plan B One-Step SNDA, Defendants argued against "speculative assertions of consumer confusion":

> That women under 17 years of age would not need a prescription to purchase Plan B One-Step but might still need a prescription to purchase the generic versions of Plan B would not be terribly confusing, especially to pharmacists and pharmacy staff who are trained to understand the differences between ages. What is more, any such differences in approval status would be the result of the statutory scheme enacted by Congress, and regulated industry understands and makes business decisions in reliance on these requirements. Indeed, drug products are marketed under a variety of different conditions that consumers navigate, and a confused consumer can ask the pharmacist for clarification.

ECF No. 333 at 11. That Defendants themselves now wish to rely on such "speculative assertions," based on nothing more than an unsupported and conclusory statement in an affidavit, does not support a stay.[11]

[11] Plaintiffs note that the Declaration of Janet Woodcock, ECF No. 91-2, does not in any way undermine FDA's finding that emergency contraception "is safe and effective and should be approved for nonprescription use for all females of child-bearing potential." *Tummino II*, 2013 U.S. Dist. LEXIS 49666, *12 (quoting statement from FDA Commissioner Margaret Hamburg, M.D., on Plan B One-Step (Dec. 7, 2011)).

Defendants have failed to show, or even make a credible argument, that retailers will be unable to comply and properly instruct employees or communicate restrictions on access to purchasers in the unlikely event that the Court's Order is overturned on appeal. This Court cannot presume that retailers – who routinely impose restrictions or availabilities on access to drugs – would somehow be unable to do so for emergency contraception. Any concern about misbranding or re-shelving is also wholly speculative, against common sense and existing practice. If the Order is reversed, retailers could easily remove any products from their shelves or, FDA could recall any products – as they have done in the past when required.[12]

2. The Government's Asserted Interest in a Drug Manufacturer's Exclusivity Does Not Support a Stay

Defendants have failed to establish that their asserted interest in conferring market exclusivity will be irreparably harmed absent a stay. Although Defendants claim this action was "not undertaken to comply with [this Court's April 5] Order," Defendants rely on the fact that they granted Teva exclusivity as a basis for granting a stay, and filed their stay motion just one day after the approval was announced.

Although Defendants caused the circumstances about which they now complain, Defendants still maintain that a stay is necessary because the regulatory process will be harmed if they are required by the Court's Order to approve generic versions of Plan B One-Step for non-prescription use without age restriction. This defies common sense. A grant of exclusivity allows a manufacturer to monopolize a market for three years, in this case, at the expense of

[12] All stores would have to do is take the drugs off the shelves and put them behind the counter so products could be returned to the company as part of a recall. As this Court is aware, following its decision on March 23, 2009, retailers had to address changes in product status issues when the denial of the Citizen Petition was vacated and the matter was remanded to the FDA to reconsider its decisions concerning the over-the-counter switch of Plan B and FDA was ordered to permit the drug manufacturer of Plan B to make it available to 17 year-olds without a prescription, under the same conditions it was then only available to women over the age of 18. *See Tummino I*, 603 F.Supp.2d at 550.

generic drugs of the same product. Thus, permitting *all* levonogestrel-based products to be available over-the-counter without point-of-sale restrictions would have the effect of driving down the cost of emergency contraception, thereby benefitting consumers and serving the public interest by resulting in greater access to less expensive products. *See e.g.*, *Biovail Corp. v. Food and Drug Admin.*, 448 F. Supp. 2d 154, 166 (D.D.C. 2006) ("[T]he public also has an interest in receiving generic competition to brand-name drugs as soon as is possible, . . . and a delay in the marketing of the generic drug could easily be against the public interest in reduced prices . . . ." (internal quotation marks, citations and alterations omitted)).

Defendants claim that despite acting on the amended SNDA as if the Court's Order did not exist, they are now entitled to use their approval of the amended SNDA to argue that they should not have to comply with the Order. Defendants seek to defend this course of conduct by criticizing this Court for "ignor[ing] the prospect that . . . Teva could file an amended SNDA, which FDA could approve, leading to a grant of exclusivity." Stay Motion at 15. Whether Teva could file an amended SNDA for the FDA to approve at some unspecified future date is irrelevant. Teva had no right to exclusivity at the time of this Court's order because the FDA had denied Teva's SNDA and therefore "the policy justification underlying the FDCA does not apply here." *Tummino II*, 2013 U.S. Dist. LEXIS 49666, *90. That Defendants willfully took action that they now claim interferes with their ability to comply with the Order simply cannot provide a basis for a stay. More important, Defendants took this action even after the Court found the "FDA did not have the authority to mandate point-of-sale restrictions on drugs approved for nonprescription sales that it found to be safe and effective for all women of childbearing age." *Id*. at *62. In blatant disregard of the Court's Order, the FDA not only perpetuated the current point-of-sale restrictions, but affirmatively added a new set of restrictions

that differ depending on if a woman is purchasing Plan B One-Step or generic equivalents of Plan B.

Moreover, Defendants' arguments as to an interest in protecting exclusivity as a general proposition and in protecting Teva's exclusivity in this case, ring hollow. The unique factual circumstances here, in which Defendants granted exclusivity when they knew that it would put them in direct conflict with a duly entered federal court order, do not undermine the broad policy goals of the exclusivity scheme. Nor can Defendants assert an interest specific to Teva. It is Defendants' conduct in regards to Teva's SNDA's that has threatened Teva's exclusivity because Defendants inextricably linked the Plan B One-Step SNDA with the denial of the Citizen Petition. Having caused the problem, Defendants cannot now rely on their attempt to fix it to support their request for a stay.

D. The Public Interest Will be Not be Served by a Stay

Where, as here, Plaintiffs are litigating a matter of serious public concern which involves the fundamental right of access to time-sensitive contraception and to make one's own decision in matters of childbearing, the public interest lies in favor of the swift execution of a judgment which promotes these interests. *Id*. at **70-71 (recognizing that this case involves the constitutional right to obtain and use contraceptives and the restriction on the sale of time sensitive levonorgestrel-based contraceptives, which affects all women, implicates this right). *See, e.g.*, *Cooper v. Town of East Hampton*, 83 F.3d 31, 36 (2d Cir. 2006) (denying stay and weighing important public interest involving party invoking constitutional protection to speaking on a matter of public concern); *Daniels v. City of N.Y.*, 138 F.Supp.2d 562, 565 (S.D.N.Y. 2001) (denying stay where public interest weighs in favor of litigating a controversial matter of serious public concern and where unnecessary delay, including stay pending appeal, is against interests

of justice and public's best interest in expeditious resolution). The risk and reality of forced unwanted pregnancy is an injury that compounds as more time elapses while emergency contraception remains subject to burdensome, scientifically unsupported and politically motivated restrictions.

Moreover, the public health, and therefore the public interest, benefits from the availability of emergency contraception over-the counter, without burdensome restrictions. *Tummino I*, 603 F. Supp. 2d at 533 (Dr. Rosenbraugh, Deputy Director of the Division of OTC drugs stated that "'[a]ny system placing barriers to access would defeat the purpose of the drug and lessen its public health potential.'"). The benefits include the potential to decrease unwanted teen pregnancy by up to 70 percent and reducing teen abortions. Id. at 529. It is ironic that an Administration that "has invested many millions of dollars to battle teenage pregnancy and fought to include contraception in [its] health plan," *Tummino II*, 2013 U.S. Dist. LEXIS 49666, *27, continues to perpetuate complicated barriers which prevent those same groups gaining timely and greater access to safe and effective birth control. The public interest also weighs in favor of holding accountable those at the FDA entrusted to protect and promote the public health with integrity.

In the absence of a stay, the Court's Order will take effect. There will be no uncertainty regarding the status of emergency contraceptives. They will, in fact, be readily available out on the shelves of local drugstores and other locations across the nation so that these safe, effective and time-sensitive drugs to prevent unintended or unwanted pregnancy are no longer wrongfully withheld from the public.

Unrestricted over-the-counter emergency contraception has been improperly withheld by the government for over a decade. Defendants have acted against the scientific evidence, based

on improper political motivation, to deprive women and girls timely access to emergency contraceptives without burdensome and arbitrary restrictions. The Court's ruling stops this improper deprivation, and the public interest favors that is should do so.

CONCLUSION

As explained herein, it is not possible for the Court to grant the stay in a manner that "secures Plaintiffs' rights." Nor have Defendants met their burden to prove any of the factors necessary to support their request. For all the reasons stated herein, Defendants' Motion for Stay of the Court's Memorandum and Order filed on April 5, 2013, should be denied.

Dated: May 6, 2013

Respectfully submitted,

/s/ *Janet Crepps*
JANET CREPPS*
Center for Reproductive Rights
120 Wall Street, 14th Floor
New York, NY 10005
(917) 637-3600

Attorneys for all Plaintiffs

ANDREA COSTELLO*
Partnership for Civil Justice Fund
617 Florida Avenue, NW
Washington, D.C. 20001
(202) 232-1180 (phone)
(202) 747-7747 (fax)
ac@justiceonline.org

KIRSTEN CLANTON*
Southern Legal Counsel, Inc.
1229 NW 12th Ave.
Gainesville, FL 32601
(352) 271-8890

Attorneys for Plaintiffs Tummino, Mahoney, Giardina, Mangan, Seguin, Tinney, Brown Churchill, Hunt, and Kelly

*Admitted *pro hac vice*